Genzyme Therapeutics Renagelo. 2

Medical Professional Patient Information

Renagel® 800 mg Table

Reimbursement

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Sevelamer hydrochloride
800 mg / 400 mg Tablets and 403 mg Capsules

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In July 2000 the FDA granted approval for a new dosage form of Renagel® - Renagel® 800 mg and 400 mg tablets. The new tablet dosage form became available in the US in September 2000. The coated, nonabsorbed tablets allow for greater dosing flexibility in lowering phosphorus.

Where We Are

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Renagel® was launched in November 1998 with a 403 mg capsule. The 403 mg capsule dosage form is also still available.

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Renagel® - the first calcium-free, aluminum-free phosphate binder - offers long-term phosphorus control in patients with end-stage renal disease (ESRD) on hemodialysis, without adding excess calcium or aluminum. Phosphorus control is critical to the quality care of all dialysis patients.

See the following information on Renagel® included in this site:

Renagel® US Full Prescribing Information

Information for Healthcare Providers

Information for Patients

Reimbursement Information

Renagel Patient Assistance Program

For additional information, contact Genzyme Medical Affairs at 800.847.0069 or 617.768.9000 (Monday - Friday, 8:00AM - 6:00PM EST).

Renagel® (sevelamer hydrochloride) is indicated for the



reduction of serum phosphorus in patients with end-stage renal disease (ERSD) on hemodialysis. Renagel® is contraindicated in patients with hypophosphatemia or bowel obstruction. In a placebo-controlled study, adverse events were similar to placebo. The most common treatment-emergent adverse events were not dose related and included diarrhea (16%), infection (15%) and pain (13%). In drug interaction studies, Renagel® had no effect on bioavailability of digoxin, warfarin, enalapril, or metoprolol. When administering any oral drug for which alteration in blood levels could have a clinically significant effect on safety or efficacy, the drug should be administered at least 1 hour before or 3 hours after Renagel®, or the physician should consider monitoring blood levels of the drug.

For additional prescribing information, click here.

Note: Information on drug therapy pertains to United States audiences only. For contact information outside the U.S., please locate a <u>Genzyme office</u> in your area/country.

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